510(k) Summary

[As described in 21 CFR 807.92]

Submitted by:
Welch Allyn, Inc.
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Contact Person:
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Date Prepared: March 13, 2012

Trade Name: Acuity® Central Monitoring Station

Common Name: Arrhythmia Detector and Alarm

Classification Reference: Class II, 870.1025, Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Product Code - DSI

Predicate Devices:
Acuity® Central Monitoring Station
Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Welch Allyn, Inc.
510(k) Number K052160

Description of the Device:

The Acuity® Central Monitoring System (Acuity System) is Welch Allyn's central monitoring solution. It consists of a central monitoring station, Acuity System software and a collection of other commercially available networking products.

The Acuity System is intended for use by clinicians for the central monitoring of neonatal, pediatric and adult patients in health care facilities. The system connects to a network of patient monitors to record and analyze physiological data being acquired by the monitors. This solution leverages networking and connectivity to obtain and distribute patient information where and when needed. The overall performance of the networked system is based upon trending and data management techniques consistent with industry practice and applicable standards.

The Acuity System is available in multiple product configurations. Acuity Systems can be customized to meet a customer's unique needs based on hospital policy, health care facility size and patient census and floor layout. In all cases, the user must carefully review the features and functionality of the Acuity System to ensure that selected configurations meet specific clinical needs. The Acuity System supports patient information management, patient vital-sign alarm and equipment alert management, patient data and waveform monitoring and review, system administration and ongoing service. Acuity System software modules and devices support adult, pediatric and neonatal patients, except where indicated below. Acuity System software can include the following optional modules:

- The Full Disclosure module stores patient data for up to 96 hours.

- The Arrhythmia Analysis module provides real-time monitoring and alarms for specific changes in cardiac rhythms. The clinician is responsible for determining the clinical significance of each detected arrhythmia event or alarm. The Arrhythmia Analysis module is *not* intended for use with neonatal patients.

- The ST Analysis module provides real-time monitoring and alarms for ST-segment deviations for patients with suspected heart disease and anomalies. The clinician is responsible for determining the clinical significance of each selected ST-segment deviation or alarm. The ST Analysis option is *not* intended for use with neonatal patients.

- The Welch Allyn Connectivity Server (WACS) module consists of a server platform on which one or more of the following software options are installed: Web Server (Acuity System patient printout files available on Web browsers), AcuityLink® (Acuity System patient information delivered to mobile devices) with Clinician Notifier Barcode Interface, HL7 Interface options, and Third Party Data Stream Interface.

Acuity System software further processes data acquired from patient monitors. Acuity Systems with the Arrhythmia Analysis module calculates heart rate using multiple ECG leads and arrhythmia analysis algorithms

The Acuity System is not directly connected to patients. It is designed to be used as a central monitoring system for a set of patient monitors that support both continuously and intermittently acquired data. Supported monitors include, but are not limited to, the following Welch Allyn devices: Propaq® Encore, Propaq CS, Propaq LT, Micropaq®, and the Welch Allyn 1500 Patient Monitor, as configured to interface with the Acuity System.

The Acuity System and distributed monitoring devices are prescription devices to be used by authorized health care professionals using standard institutional procedures and standards of care for patient monitoring. Staff training in the operation of the Acuity System and the patient monitoring devices connected to it is essential for optimal use. Users should be skilled at the level of a technician, nurse, physician, health care provider or medical specialist, with the knowledge and experience to acquire and interpret patients' vital-signs data. Individuals using the Acuity System should be familiar with its operation as described in the manual, and they should understand all warnings and cautions in the manual.

Indications for Use:

Indications for Use:

The Acuity® Central Monitoring Station is intended to be used by clinicians for the central monitoring of neonatal, pediatric, and adult patients in health care facilities.

In addition to the central monitoring of patient data, waveforms, alarms and alerts, the Acuity software can include operational modules to provide extended recording of patient data (Full Disclosure), arrhythmia monitoring and ST analysis.

- Full disclosure stores patient data for up to 96 hours
- Arrhythmia monitoring module provides real-time monitoring and alarms for specific changes in cardiac rhythms. The clinician is responsible for determining the clinical significance of each detected arrhythmia event or alarm. The arrhythmia module is not intended for use with neonatal patients.
- ST analysis module provides real-time monitoring and alarms for ST segment deviations, from a reference beat, for patients with suspected heart disease and anomalies. The clinician is responsible for determining the clinical significance of each selected ST segment deviation or alarm. The ST analysis module is not intended for use with neonatal patients.

Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate device; minor modifications and additions to software and hardware were made to the Acuity® Central Monitoring Station for user enhancements.

Non-Clinical Tests:

Verification and validation were conducted to ensure expected performance of the Acuity® Central Monitoring Station.

The Acuity® Central Monitoring Station was tested to evaluate its safety and effectiveness based on the following standards:

- IEC 60601-1-1: 2000 Medical Electrical Equipment – Part 1: General requirements for safety - collateral standard: Safety Requirements for Medical Electrical Systems
- IEC60950-1: 2005 Information Technology Equipment – Safety – Part 1: General Requirements
- IEC 60601-1-2: 2007 - Medical Electrical Equipment – Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test
- ISO 14971: 2007 - Medical devices - Application of risk management to medical devices
- IEC 62304: 2006 - Medical device software -- Software life cycle processes
- ANSI/AAMI EC57: 1998 - Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- IEC 60601-1-4: 2000 - Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: General Requirements for Programmable Electrical Medical Systems

Clinical Performance Data:

No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

Conclusion:

Based on the information presented in this 510(k) premarket notification, Welch Allyn's Acuity® Central Monitoring Station is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed device cited in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 10 2012

Welch Allyn, Inc.
c/o Mr. Kevin Crossen
Director Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K120774
Trade/Device Name: Acuity® Central Monitoring Station
Regulatory Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detection and alarms (including ST-segment and alarm)
Regulatory Class: II (two)
Product Code: 74 DSI
Dated: March 13, 2012
Received: March 14, 2012

Dear Ms. Crossen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

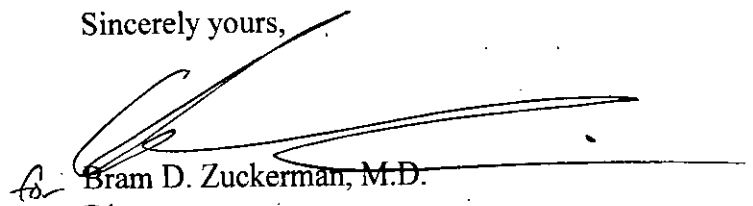
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120774

Indications for Use

510(k) Number (if known): K_____

Device Name: Acuity® Central Monitoring Station

Indications for Use:

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In addition to the central monitoring of patient data, waveforms, alarms and alerts, the Acuity software can include operational modules to provide extended recording of patient data (Full Disclosure), arrhythmia monitoring and ST analysis.

- Full disclosure stores patient data for up to 96 hours
- Arrhythmia monitoring module provides real-time monitoring and alarms for specific changes in cardiac rhythms. The clinician is responsible for determining the clinical significance of each detected arrhythmia event or alarm. The arrhythmia module is not intended for use with neonatal patients.
- ST analysis module provides real-time monitoring and alarms for ST segment deviations, from a reference beat, for patients with suspected heart disease and anomalies. The clinician is responsible for determining the clinical significance of each selected ST segment deviation or alarm. The ST analysis module is not intended for use with neonatal patients.

Prescription Use (Part 21 CFR 801 Subpart D) ___x___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of ~~Device~~ Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120774